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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,234	01/11/2002	Paola Elisabettini	DI-5782	8974

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 04/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,234	ELISABETTINI ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/28/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6-8, 11-18,20,21,24-29,44,47.48,50-54 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Reinhardt et al. (US Pat. 5,211,643).

Reinhardt et al. expressly discloses a two part solution which is stored in a two chamber container used for CAPD in which concentrate A has a pH of 7.35 to 7.4 and contains 76 mmol of sodium hydrogen carbonate and concentrate B has a ph of 5.5 and contains 196 mmol of sodium chloride, 3.0 mmol of calcium chloride and 1.66 mmol of glucose falling within the scope of applicant's claims (Example 1, Column 6, lines 65-68, Column 2, lines 1-53, Figure 1).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re Fitzgerald, 205 USPQ

594 (CCPA 1980). See also In re May, 197 USPQ 601, 607 (CCPA 1978). See also Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Claims 1,11,15,16,44,52 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Watanabe et al. (US Pat 5,122,516).

Watanabe et al. expressly discloses a two part composition which are stored separately in which first composition contains sodium, potassium and the second composition contains sodium and bicarbonate which is used for blood dialysis falling within the scope of applicant's claims (Column 6, lines 13-68, Columns 7-10).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re Fitzgerald, 205 USPQ 594 (CCPA 1980); In re May, 197 USPQ 601, 607 (CCPA 1978); Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's argument that Watanabe discloses a different use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Examiner reminds Applicant that this is a 102/103 inherency rejection, as such, the Graham v. John Deere factors are not applicable. As such, the alleged advantages do not overcome the rejection herein. The burden is on Applicant to show

that the prior art composition or product does not exhibit said advantages or cannot be used for the intended uses.

Claims 1-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isono et al. (US Pat. 5,871,477) in view of Watanabe et al. (US Pat. 5,122,516), Feriani et al. (US Pat. 4,630,727), van Bommel et al. and Reindardt et al. (US Pat. 5,211,643).

Isono et al. disclose a two part dialysis composition, containing bicarbonate and electrolyte, in which a portion of the electrolyte, for example sodium, can be in the bicarbonate part where the concentration of sodium is 90 to 150 mEq/L (Column 4, lines 60-68 , Column 5, lines 1-15, Column 8-65, Column 10, lines 44-58, Column 14, lines 10-68, Column 19, lines 12-68, column 20).

Watanabe et al. teach a two part composition, the first composition which contains an acid pH adjusting agent and sodium and the second composition which contains sodium and bicarbonate, which are stored separately and used for blood dialysis (Column 6, lines 13-68, Columns 7-10). A preferred embodiement is taught in which potassium is listed as a component in first composition but not the second composition (Column 6, lines 13-68, Columns 7-10).

Feriani et al. teach a two part composition contained in a twin-chamber bag in which the first chamber is filled with a bicarbonate-containing fluid and the second chamber is filled with an acid fluid (Abstract, Figures 1,2). An embodiement is taught where potassium is listed as a component in the bicarbonate containing solution but is not listed in the acid fluid (Column 6, lines 15-44). It is taught that the composition may be used for dialysis, hemofiltration and infusion (Column 6, lines 54-55). It is taught that for safety reasons it is preferred to have the bicarbonate in the compartment which has the discharge duct to prevent the acid part from being administered to the patient unmixed (Column 7, lines 3-21).

van Bommel et al. teach that hemodialysis and continuous renal replacement therapy can use the same fluids (Pgs. 271, Table 2, 272).

Reinhardt et al. discloses a two part solution which is stored in a two chamber container used for CAPD in which concentrate A has a pH of 7.35 to 7.4 and contains 76 mmol of sodium hydrogen carbonate and concentrate B has a ph of 5.5 and contains 196 mmol of sodium chloride, 3.0 mmol of calcium chloride and 1.66 mmol of glucose falling within the scope of applicant's claims (Example 1, Column 6, lines 65-68, Column 2, lines 1-53, Figure 1). It is disclosed solution B contains calcium and magnesium salts and concentrate A contains sodium hydrogen bicarbonate and that the level of acidity for the caramelization of glucose determines in which concentrates the remaining components, i.e. potassium chloride, sodium chloride and the like are placed (Column 6, lines 54-64). It is disclosed for the complete dialysis solutions the operative range for potassium is 04 mval/l and the preferred range is 1-3 mval/l (Column 4, lines 45-54).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a two-part composition comprising potassium in both the bicarbonate part and electrolyte part. However, the prior art amply suggests the same as it is known in the art to have two-part compositions in which potassium is contained either in the acid/electrolyte part or the bicarbonate part. As such, it would have been well within the skill of one of ordinary skill in the art to prepare a two-part composition in which potassium is contained in the bicarbonate part and/or the acid/electrolyte part as desired. Further, it would have been well within the skill of one of ordinary skill in the art to have varying pH's in the bicarbonate part and acid/electrolyte part, including pH's falling within the claimed pH's, depending on the desired amounts of acid and bicarbonate in each part and the desired final pH of the mixture of the two parts. Also, it

would have been well within the skill of and one of ordinary skill in the art would have been motivated to use a double chambered bag in which a first component cannot be administered to a patient without mixing with the second component for purposes of patient safety. Finally, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to use the two-part compositions for hemofiltration, including renal replacement therapy and infusion, with the expectation that the prior art dialysate composition would be suitable for the same.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

The prior art discloses that it is known to have two-part compositions in which sodium is contained in the acid/electrolyte part and the bicarbonate part as well as potassium being in both, one or neither of the parts. As such, it would have been well within the skill of one of ordinary skill in the art to prepare a two-part composition in which sodium and potassium is contained in the bicarbonate part and/or the acid/electrolyte part as desired. See In re Burhans, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the

absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.). Applicant has not shown any new or unexpected results of having equimolar amounts of sodium or potassium in one or both of the concentrates. Further, 15-40 mmol/l falls with the range of 160 mmol/L or less. With respect to amounts of about 100 mmol/L to about 160 mmol/L it is well within the skill of one of ordinary skill in the art, since it is disclosed that the sodium electrolyte may be in both compartments, to provide any amount of sodium including equimolar amounts, provided that the combination results in a range of 160 mmol/L or less. Applicant provides no evidence of new or unexpected results by having potassium in one or both of the concentrates. The prior art discloses the use of potassium falling within the claimed physiological range, as such, it would have been well within the skill in the art to provide a physiological amount in one or both of the concentrates as desired to arrive at the desired physiological concentration in the mixed solution. Reinhardt et al. disclose the use of a two chamber container (See figure 1) which separate stores the two parts in which the upper portion cannot be administered to the patient without first breaking the seal between the two compartments. With respect to Applicant's safety considerations, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 173 USPQ 560 (CCPA 1972); In re Dillon, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991) (discussed below). Further, the prior art discloses that, contrary to Applicant's arguments, the fluids used in hemodialysis can be used in continuous renal replacement therapy. Finally, since the two part solutions are supposed to be mixed prior to administration, it would have well within the skill of and one of ordinary skill in the art would

have been motivated to use a container, such as disclosed in

Reinhardt et al. which prevents administration of the upper component without mixing with the lower component since the two part solutions are required to be mixed together to form the final use solution.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
April 18, 2005

JOHN PAK
PRIMARY EXAMINER
GROUP 1600